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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/744,489	01/23/2001	Lisa Joanne Drewe	41577/252464	5644

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EXAMINER

CHUNDURU, SURYAPRABHA

ART UNIT	PAPER NUMBER
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1637

DATE MAILED: 10/01/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/744,489

Applicant(s)

DREWE ET AL.

Examiner

Suryaprabha Chunduru

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 16 July 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,2,5,6,8-12,14,16 and 18-24 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-2, 5-6, 8-12, 14, 16, 18-24 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☒ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date 7/16/04
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

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DETAILED ACTION

1. Applicants' response to the office action and the amendment filed on July 16, 2004 has been entered.
2. The instant application filed on January 23, 2001, is a 371 of PCT/GB99/02317 filed on July 19, 1999.
3. The second Preliminary amendment and Preliminary amendment filed on 8/11/2003 and 10/17/2003 have been entered and considered. Claims 1-2, 5-6, 8-12, 14, 16, and 18-24 are pending.

Response to arguments

4. Applicants' response to the office action is fully considered and found persuasive.
5. With reference to the rejections made in the previous office action under 35 USC 103(a), Applicants' arguments are fully considered and found persuasive. The rejection is withdrawn herein in view of the arguments and new grounds of rejections.

New Grounds of Rejections

Claim Rejections - 35 USC § 102

6. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-2, 5-6, 9, 12, 22-24 are rejected under 35 U.S.C. 102(b) as being anticipated by Seeger et al. (Biotechniques, Vol. 23, No.3, page 512-514, 516,517, 1997).

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Seeger et al teach a method of claims 1, and 6, for detecting the presence of a target nucleic acid containing purine-rich region (see page 216, col. 1, line 4-7, col. 2, line 1-4), in a sample or purine -rich region is introduced in to the target during PCR with one of primers containing plurality of purines (page 513, col.2 paragraphs 3-5 under PCR procedure section) comprising

(a) amplifying said target (which includes purine-rich region) (see page 2798, col. 1, paragraph 1-2 under sub-heading analysis of PCR products);

(b) during step(a) contacting the sample with peptide nucleic acid probe (PNA) that binds to said target (see page 513, col.1, paragraph 2 of the sample preparation procedure sub heading, col. 2, paragraphs 1-5 of PCR procedure subtitle, col. 3, paragraph 2 under results and discussion);

(c) detecting the presence of target by detecting the target: probe complex (triplex-structure) (see page 513, col. 3, lines 5-10);

With regard to claim 2, Seeger et al. teach that said PNA is bis-PNA (see page 513, col. 3, paragraph 1 under results and discussion section);

With regard to claim 5, 22, Seeger et al. teach that the amplification reaction is a PCR (see page 513, col.2, paragraphs 1-5 under PCR procedure section);

With regard to claim 9, 23, Seeger et al. teach that said PNA is immobilized (page 513, col. 1, paragraph 2 of the sample preparation procedure section);

With regard to claim 12 and 24, Seeger et al. teach that the triplex structure (target-probe complex) is detected using a gel retardation detector (see page 513, col. 3, lines 5-10).

Claim Rejections - 35 USC § 103

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6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 14-16, 18-21 are rejected under 35 U.S.C. 103(a) as being unpatentable over Seeger et al. (Biotechniques, Vol. 23, No.3, page 512-514, 516,517, 1997) in view of Felgner et al. (USPN.6,165,720).

Seeger et al teach a method for detecting the presence of a target nucleic acid containing purine-rich region (see page 216, col. 1, line 4-7, col. 2, line 1-4), in a sample or purine-rich region is introduced in to the target during PCR with one of primers containing plurality of purines (page 513, col.2 paragraphs 3-5 under PCR procedure section) comprising

(a) amplifying said target (which includes purine-rich region) (see page 2798, col. 1, paragraph 1-2 under sub-heading analysis of PCR products);

(b) during step(a) contacting the sample with peptide nucleic acid probe (PNA) that binds to said target (see page 513, col.1, paragraph 2 of the sample preparation procedure sub heading, col. 2, paragraphs 1-5 of PCR procedure subtitle, col. 3, paragraph 2 under results and discussion);

(c) detecting the presence of target by detecting the target: probe complex (triplex-structure) (see page 513, col. 3, lines 5-10);

Seeger et al. teach that said PNA is bis-PNA (see page 513, col. 3, paragraph 1 under results and discussion section); the amplification reaction is a PCR (see page 513, col.2, paragraphs 1-5 under PCR procedure section);said PNA is immobilized (page 513, col. 1, paragraph 2 of the sample preparation procedure section); the triplex structure (target-probe complex) is detected using a gel retardation detector (see page 513, col. 3, lines 5-10).

However Seeger et al. did not teach detection of the target using a wave guide detector.

Felgner et al. teach a method for detecting a target nucleic acid using PNA probe labeled with fluorescent labels (FRET labels) and monitoring the hybridization and detecting the signal by a wave guide detector (surface plasmon resonance detector), spectrofluorometer (see col. 14, line 21-58). Felgner et al. also teach a kit comprising PNA, target nucleic acid (plasmid DNA comprising a complementary sequence) (see col. 11, line 61-67, col. 12, line 1-9).

Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the method of detecting a target nucleic acid comprising purine-rich region as taught by Seeger et al. with the step of adding a wave guide detector as taught by Felgner et al. to achieve expected benefit of developing an enhanced and improved method for detecting a target nucleic acid in a sample because Felgner et al. the use of FRET assay in

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monitoring the formation and dissociation of triple helices (See col. 14, line 24-58). An ordinary practitioner would have been motivated to modify the method of detecting a target nucleic acid as taught by Seeger et al. by incorporating the fluorescence resonance energy transfer labels and detection by spectrofluorometer to develop a method that would provide a sensitive detection assay for monitoring and quantitating a target nucleic acid.

Conclusion

No claims are allowable.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Suryaprabha Chunduru whose telephone number is 571-272-0783. The examiner can normally be reached on 8.30A.M. - 4.30P.M, Mon - Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Benzion can be reached on 571-272-0782. The fax phone numbers for the organization where this application or proceeding is assigned are 703-872-9306 for regular communications and - for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

^{8/22}
Suryaprabha Chunduru
September 28, 2004


JEFFREY FREDMAN
PRIMARY EXAMINER

9/29/04